CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE

BOARD OF PHARMACY

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APPLICATION FOR IN-STATE PHARMACY PERMIT
INSTRUCTION SHEET

When to File Application

This is the application for licensure of a Retail or Hospital Pharmacy located in Delaware – that is, In-State Pharmacy.

- A Pharmacy–Hospital license is for the in-house pharmacy that dispenses to hospital in-patients.
- A Pharmacy–Retail license is for any of these types of outlets:
  - Community Pharmacy – A retail pharmacy that dispenses directly to patients and is not a nuclear or specialty institutional pharmacy.
  - Nuclear Pharmacy – A pharmacy that provides radiopharmaceutical services or an appropriate area set aside in institutional facility (Section 13.2 of the Board's Rules and Regulations).
  - Specialty Institutional Pharmacy – Institutional pharmacies which provide specialized pharmacy services not generally obtainable from other pharmacies. Examples are short term or primary care treatment facilities that have onsite pharmacies on site such as outpatient chemotherapy centers, primary treatment centers, free standing emergency rooms, rapid in/out surgical centers and certain county health programs (Section 20.0 of the Board's Rules and Regulations).

File this application when applying for an initial license for any of the above types of in-state pharmacy licenses OR re-applying when a previous Delaware pharmacy license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when an in-state pharmacy already licensed in Delaware:

- Changes ownership (controlling interest), or
- Relocates

Requirements for *All* Applicants

Please read and follow instructions carefully. Failing to follow instructions will delay processing of your application.

☐ Submit completed, signed and notarized *Application for In-State Pharmacy Licensing*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Arrange for the pharmacist-in-charge (PIC) to sign the **PHARMACIST-IN-CHARGE ACKNOWLEDGMENT** section.
- A PIC must hold a current Delaware Pharmacist license.
- A PIC may serve as a PIC for only one pharmacy at a time.
- The PIC of a Nuclear Pharmacy must be a Qualified Nuclear Pharmacist. He/she is responsible for all Pharmacy operations and must be personally on the premises at all times that the Pharmacy is open for business.
- If the PIC has not previously served as a pharmacist-in-charge in Delaware, he or she must appear personally at a regularly scheduled Board meeting within 90 days of assuming the position.
- A PIC must complete the *Pharmacist-in-Charge Self-Inspection* form by February 1 of each year.
- PIC changes must be reported to the Board of Pharmacy within 10 days of the change. Use the *Report of Pharmacist-in-Charge Change* form.
- To receive news and alerts from the Delaware Board, a current email address is *essential*. As a Delaware-licensed Pharmacist, a PIC can keep his/her contact information up-to-date online at Change Contact Information.

☐ Enclose the non-refundable processing fee by check or money order made payable to the "State of Delaware."
- Applications submitted without the required fee will be rejected.

☐ Enclose a separate sheet showing the information at right for *each* owner, corporate officer, pharmacist and pharmacy employee listed on the application:

- Name
- Data of Birth
- Social Security Number
- Mailing Address

☐ Enclose three sets (copies) of the plans for the pharmacy department.
- Plans must be drawn to scale and should include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe, security systems, and counters. For specific requirements, refer to 24 *Del.C.* §2533 and Section 3.0 of the Board's Rules and Regulations, both available at www.dpr.delaware.gov.
- Plans must also show the type of alarm system installed and the name, address, and phone of the provider.
- If the plans are for a nuclear pharmacy, the plans must show the radioactive storage and product decay area.

☐ Enclose sample patient profile that meets the requirements of Section 5.0 of the Board's Rules and Regulations.
***Label* each of the following required items on the sample profile:**
- ☐ Patient's family name and first name
- ☐ Patient's address and phone number (or location in institution)
- ☐ Patient's gender and age or date of birth
- ☐ Original date the medication is dispensed following receipt of the prescription
- ☐ Number or designation for prescription
- ☐ Prescriber's name
- ☐ Name, strength, quantity, directions and refill information of drug dispensed
  - Appropriate directions must also be present if medication is for patients in institutions.
- ☐ Initials of dispensing pharmacist and date of dispensing medication as a refill if those initials and date are not recorded on original prescription
- ☐ If patient refuses to give all or part of the required information, the pharmacist shall indicate and initial in the appropriate area
- ☐ Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug
- ☐ Annotate the patient's
  - allergies, idiosyncrasies, chronic diseases
  - frequently used over-the-counter medications

  If the answer is none, this must also be shown on the profile.

Additional Requirement for Nuclear Pharmacies

☐ Submit a copy of your approved Delaware Office of Radiation Control or Nuclear Regulatory Commission license.

Inspection Requirement

In addition to meeting all the requirements above, the pharmacy must be inspected before opening. A pharmacy representative ***must notify the Board office*** when the pharmacy is ready for inspection. When the pharmacy passes the final inspection, the Board office will issue the license.

Reporting Remodeling of an In-State Pharmacy

If an in-state pharmacy will be remodeling but ***there is no change in ownership nor location***, file an *Application for In-State Remodeling Permit* instead of the *Application for In-State Pharmacy Permit.*

Reporting an In-State Pharmacy Name Change

If the in-state pharmacy's name changes but ***there is no change in ownership nor location***, it is not necessary to submit an *Application for In-State Pharmacy Permit*. Instead, submit:

☐ Letter notifying the Board of the change that includes the pharmacy's old name, new name, license number and effective date of change.

☐ Duplicate license fee by check or money order made payable to the "State of Delaware."
- The duplicate license will show the new name, but the license number will not change.

Controlled Substances Registration

If the in-state pharmacy stores and/or dispenses controlled substances, a separate *Controlled Substances Application for Facilities* is required.

Before dispensing controlled substances in Delaware, a pharmacy must have a Delaware Pharmacy permit, Delaware controlled substance registration and federal DEA permit. All pharmacies dispensing controlled substances must register and report to the Delaware Prescription Monitoring Program (PMP).

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For Board of Pharmacy Use Only
- ☐ **Verification**
- ☐ **Background**
- ☐ **Office Approval**
- ☐ **Inspection**

APPLICATION FOR IN-STATE PHARMACY PERMIT

TYPE OF APPLICATION

1. Select the items that describe the type of application:

   ☐ Initial Application –
   - ☐ This pharmacy has never held a Delaware Pharmacy license.
   - ☐ This pharmacy previously held Delaware Pharmacy license number **A** ____**-** _____ that has lapsed and is no longer renewable.

   ☐ Application Due to Change of Ownership – Pharmacy license number **A** ___**-** _____

   ☐ Application Due to Relocation – Pharmacy license number **A** ___**-** _____

2. Select type of pharmacy: ☐ **Retail** – Select type of retail outlet: ☐ **Hospital** (In-patient dispensing *only*)
   - ☐ Community
   - ☐ Nuclear
   - ☐ Specialty Institutional

CONTACT AND LOCATION INFORMATION

3. Name of Business (as it should appear on license): _____

4. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

5. ***Location* Address**: _____
   Street (*No PO Boxes*) — Note: If you are reporting relocation, this is the *new* location.

   _____ _____ _____
   City — State — Zip

6. Location Phone: _____

7. ***Mailing* Address** (*if different from physical location*): _____

   _____ _____ _____
   City — State — Zip

8. Enter the name and email of the person who should be contacted for information about this application. The contact may be a representative in the corporate/district, an owner or the Pharmacist-in-Charge. An *Application Receipt* and any other correspondence about this application will be sent to the email address you enter here.

   Contact Name: _____ Email: _____

LICENSURE INFORMATION

9. Will you store and/or dispense controlled substances?
   Yes ☐ No ☐

Before dispensing controlled substances in Delaware, a pharmacy must have a Delaware Pharmacy permit, Delaware controlled substance registration and federal DEA permit. All pharmacies dispensing controlled substances must register and report to the Delaware Prescription Monitoring Program (PMP).

10. If applying as a Nuclear Pharmacy, do you have a Delaware Office of Radiation Control and/or Nuclear Regulatory Commission license? Yes ☐ No ☐ **If yes, submit a copy of your Delaware Office of Radiation Control or Nuclear Regulatory Commission license**.

OWNERSHIP INFORMATION

11. Type of Business Owner (check one):

☐ Sole Proprietor – Continue with Question 12
☐ Individual with federal employee identification number – Continue with Question 12.
☐ Partnership – **Skip to** Question 13.
☐ Corporation – Enter Date of Corporate Charter: _____ **Skip to** Question 13.

12. Enter the following information about the owner and then skip to Question 14.

Full Name: _____

Date of Birth: _____ Social Security Number: _____

Mailing Address: _____

_____ _____ _____
City State Zip

13. If a partnership, list ***all active partners***. If a corporation, list ***all principal officers***.

FULL NAME	TITLE

Enclose a separate sheet listing name, date of birth, Social Security Number and mailing address for each person listed above.

14. Do you understand that the Board must be notified within ten days of a change of ownership? Yes ☐ No ☐

PHARMACIST AND EMPLOYEE INFORMATION

15. Enter the following information about the Pharmacist-in-Charge:

Full Name: _____ Delaware License Number: **A1-** _____

Arrange for the person named above to sign the *Pharmacist-in-Charge Acknowledgment* below. If this person has not previously served as a Pharmacist-in-Charge in Delaware, he or she must appear personally before the Board within 90 days of assuming the position.

PHARMACIST-IN-CHARGE ACKNOWLEDGMENT

I understand that I am responsible for conducting and managing the prescription department in compliance with all applicable state and federal laws.

Have you read and understood your responsibilities in Section 3.1 of the Board's Rules and Regulations? Yes ☐ No ☐

Do you agree to notify the Board of Pharmacy in writing within 10 days of your termination as pharmacist-in-charge? Yes ☐ No ☐

Pharmacist-in-Charge Signature: _____ Delaware License **A1 -** _____

Email: _____

To receive news and alerts from the Delaware Board, a current email address is *essential*.
Keep all of your contact information up-to-date online at Change Contact Information.

16. List all other registered pharmacists who will be dispensing at the Pharmacy.

FULL NAME	LICENSE NUMBER
	A1-_____
	A1-_____
	A1-_____
	A1-_____
	A1-_____

Enclose a separate sheet listing name, date of birth, Social Security Number and mailing address for each person listed above.

17. List all unregistered employees who will be working in the Pharmacy.

FULL NAME	EMPLOYMENT START DATE

Enclose a separate sheet showing name, date of birth, Social Security Number and mailing address for each person listed above.

INFORMATION ABOUT PHARMACY SERVICES

18. Check all pharmacy services offered:

- ☐ Dispense non-controlled substances
- ☐ Dispense controlled substances
- ☐ Sterile compounding – check all that apply:
  - ☐ LOW RISK
  - ☐ MEDIUM RISK
  - ☐ HIGH RISK
- ☐ Non-sterile compounding
- ☐ Wholesale distribution
- ☐ Pharmaceutical manufacturing
- ☐ Mail order
- ☐ Long-term care
- ☐ Nuclear

19. Will you offer any of the above services to patients who are not in Delaware? Yes ☐ No ☐

20. Will you provide ***non-sterile*** compounding? Yes ☐ No ☐ If yes, check all that apply:
- ☐ Pursuant to patient-specific prescription
- ☐ In bulk – compounding multiple doses from a single source or batch
- ☐ In bulk – for office use

21. Will you provide ***sterile*** compounding? Yes ☐ No ☐ If yes, check all that apply:
- ☐ Pursuant to patient-specific prescription
- ☐ In bulk – compounding multiple doses from a single source or batch
- ☐ In bulk – for office use

22. Will you compound in bulk, whether sterile or non-sterile? Yes ☐ No ☐ If yes, indicate your largest number of doses from a single batch: ☐ 24 or fewer ☐ 24 – 49 ☐ 50 – 100 ☐ 100 or more

23. Will you provide ***sterile*** compounding? Yes ☐ No ☐ If yes, check all types of substances compounded:

☐ Total parenteral nutrition (TPN)	☐ Aqueous inhalant solutions for respiratory
☐ Parenteral antibiotics	☐ Parenteral antineoplastic agents
☐ Parenteral electrolytes	☐ Parenteral vitamins
☐ Irrigating fluids	☐ Ophthalmic preparations
☐ Parenteral analgesics	☐ Other: _____

INFORMATION ABOUT OUTSOURCING SERVICES

24. Will this pharmacy compound sterile drugs without a prescription and distribute them in Delaware? Yes ☐ No ☐ ***If yes,*** **the facility is an outsourcing facility as defined in Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act *You must complete and submit an Application for Outsourcing Facility* in addition to this application.**

INFORMATION ABOUT PHARMACY OPERATION

25. Pharmacy Department hours:

Weekdays	_____ AM to _____ PM
Saturday	_____ AM to _____ PM
Sunday	_____ AM to _____ PM
Holidays	_____ AM to _____ PM

26. Enter Hours of Business Site:

Weekdays	_____ AM to _____ PM
Saturday	_____ AM to _____ PM
Sunday	_____ AM to _____ PM
Holidays	_____ AM to _____ PM

27. The Prescription Department must occupy at least 250 square feet of floor space excluding a storeroom. The prescription counter must be at least 18 inches wide with four linear feet kept clear and free of all merchandise for each pharmacist working concurrently. The aisle behind the counter must be at least 30 inches wide and shall be kept free of obstruction at all times. Are these requirements met? Yes ☐ No ☐

28. Will the pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices? Yes ☐ No ☐

29. Will the pharmacy have a dispensing area of adequate size and space for proper compounding, dispensing, and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel? Yes ☐ No ☐

30. The area in which drugs and devices are stored must be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit. Will the pharmacy have sufficient environmental control, i.e. lighting, ventilation, heating, and cooling, to maintain the integrity of drugs and devices? Yes ☐ No ☐

31. The sink in the pharmacy area must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized. Will the pharmacy contain a sink with hot and cold running water? Yes ☐ No ☐

32. Refrigerators and freezers (where required) will be maintained at the USP/NF range: Refrigerator – 36 ° to 46 ° Fahrenheit; Freezer – minus 4 ° to plus 14 ° Fahrenheit. Will the pharmacy have suitable refrigeration with appropriate monitoring device? Yes ☐ No ☐

33. An area must be provided to afford the patient privacy from auditory detection by any unauthorized person(s. In most settings, an area partitioned with a minimum of 9 square feet will satisfy this requirement. Will the pharmacy have an area which assures patient privacy to facilitate counseling? Yes ☐ No ☐

34. A sign, with letters not less than 3/4" in height, in the vicinity of the prescription department and visible to the public must list the names of the pharmacists employed at that pharmacy or the name of the pharmacist on duty. Will the pharmacy meet this requirement? Yes ☐ No ☐

35. Do the floor plans for the pharmacy include the type of alarm system installed and the name, address, and phone number of the provider? Yes ☐ No ☐

36. The pharmacy must have floor-to-ceiling physical barriers, motion detectors, and surveillance cameras that meet the standards in Section 5.0 of the Uniform Controlled Substances Act Regulations. Will the pharmacy meet this requirement? Yes ☐ No ☐

37. No one but a pharmacist is allowed to unlock and lock the prescription department. Will the pharmacy meet this requirement? Yes ☐ No ☐

38. Each pharmacy is required to maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronic) appropriate to the practice and to the care of the patient served. Will the pharmacy meet this requirement? Yes ☐ No ☐ If yes, explain how you will assure that current information is readily available (e.g., FDA website):_____

39. The pharmacy must maintain the following records:
    - the original of every prescription compounded or dispensed at the pharmacy for a period of at least three years
    - patient profile record for a period at least one year from the date of the last entry in the profile record unless it is also used as a dispensing record.
    - *(Nuclear Pharmacies only)* records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with NRC statute(s) and regulation(s)

    Will the pharmacy meet these recordkeeping requirements? Yes ☐ No ☐

40. When receiving a new prescription, a pharmacist (or pharmacy intern under the direct supervision of a pharmacist) must examine the patient profile before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. If a potential harmful reaction or interaction is recognized, the pharmacist must take appropriate action to avoid or minimize the problem, including consultation with the physician as necessary. Will the pharmacy meet this requirement? Yes ☐ No ☐

- **Enclose three sets (copies) of the plans for the pharmacy department. Plans must be drawn to scale and should include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe, security systems, and counters. If applying as a Nuclear Pharmacy, the plans must show a radioactive storage and product decay area.**
- **Enclose a sample patient profile. See the Instruction Sheet for checklist of items that must appear on the sample.**

DISCLOSURES

41. Have any of the owners, corporate officers, pharmacists or unregistered employees listed on this application ever been convicted of or entered a plea of guilty or *nolo contendere* (no contest) to any felony, misdemeanor or any other criminal offense, including any offense for which they have received a pardon, in any jurisdiction? Yes ☐ No ☐ **If yes, submit a certified copy of the criminal history record from any jurisdiction where they have been convicted or pardoned. For information on obtaining a Delaware criminal history record, see State Bureau of Identification.**

42. Are any of the owners, corporate officers, pharmacists or unregistered employees listed above presently charged with committing a felony? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet**.

43. Have any of the owners, corporate officers or pharmacists listed above ever applied for a pharmacy permit or controlled substances registration in any State and had the application denied? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet.**

44. Has any of the owners, corporate officers or pharmacists listed above ever been the subject of any disciplinary action (formal or informal) by any federal or state agency or any hospital credentials committee including, but not limited to, revocation or suspension of a controlled substance registration or is any such action pending? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and enclose any relevant documents.**

DUTY TO REPORT

45. To obtain a Delaware permit as an In-State Pharmacy, you must certify that the owners, corporate officers, pharmacists and unregistered persons listed on this application understand that they each have a ***mandatory*** obligation to file a written report with the Delaware Board of Medical Licensure and Discipline within 30 days if they have any reason to believe that a Delaware-licensed medical practitioner is (or may be) guilty of unprofessional conduct as defined in 24 *Del. C.* §1731 OR that he/she is (or may be):
    - medically incompetent
    - mentally or physically unable to engage safely in the practice of medicine
    - excessively using or abusing drugs including alcohol.

    I certify that the owners, corporate officers and pharmacists listed on this application have read the provisions of 24 *Del. C*. §1730, 24 *Del. C.* §1731 and 24 *Del. C*. §1731A and that they understand their *duty to report*. Yes ☐ No ☐

46. To obtain a Delaware permit as an In-State Pharmacy, you must certify that the owners, corporate officers, pharmacists and unregistered persons listed on this application understand that they each have a ***mandatory*** obligation to make an immediate oral report to the Delaware Department of Services for Children, Youth and Their Families if they know of, or they suspect, child abuse or neglect under Chapter 9 of Title 16 and to follow up with any requested written reports.

    I certify that the owners, corporate officers and pharmacists listed on this application have read 16 *Del. C.* §903 and that they understand their *duty to report*. Yes ☐ No ☐

    When your application is <u>complete</u>, please allow 4-8 weeks to receive your permit. A <u>complete</u> application is one that includes all required documentation and correct payment. Applications that are not <u>complete</u> within 12 months of filing may be considered abandoned and discarded.

AFFIDAVIT

I hereby swear or affirm that the foregoing statements are correct and do hereby agree to abide by the pharmacy laws of the State of Delaware and to all rules and regulations of the Delaware State Board of Pharmacy.

Signature:_____ Date: _____

Print Name:_____ Position: _____

State: _____ County: _____

Sworn or affirmed before me a Notary Public this_____ day of _____ 2_____

Notary Public: _____

SEAL

My commission expires on _____

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED FEE WILL BE REJECTED.